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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/933,680 | 08/22/2001 | Robert J. Levy | T1118/20031 | 7085 |
| 3000 | 7590 | 05/10/2004 | EXAMINER | |
| CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 12TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212 | | | SAUCIER, SANDRA E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,680

Applicant(s)

LEVY ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-12 and 34-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46 and 47 is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-12, 34-42, 45, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) 43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/03 has been entered.

DETAILED ACTION

Claims 1-6, 10-12, 34-49 are pending and are considered on the merits.

Claim 1, line 4, has "and wherein" which does not appear to be canceled in the faxed document. Please clarify in the response.

Claims 2 and 40 are duplicates.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 10, 11, 34-37, 40-42, 45, 48 and 49 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,931,546 [A].

The claims are directed to a method of treating an implantable biological tissue comprising contacting the tissue with a carbohydrate oxidizing agent and a protein cross-linking agent such as glutaraldehyde.

The references are relied upon as explained below.

US 4,931,546 discloses in example 4 a process for treating a collagen implant comprising contacting collagen with periodic acid and then with glutaraldehyde. While collagen might not be interpreted as classically defined

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tissue, applicant have defined tissue in one embodiment as being able to be constructed from extracellular matrix (page 10, l. 14). Collagen is a component of extracellular matrix, and as such the lens of the reference is considered to be a tissue construct and fall within the definition of the specification.

Claims 1-6, 10-11, 34, 38-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bernacca et al. [U]

The claims are directed to a method of treating an implantable tissue comprising contacting the tissue with a heterofunctional azide reagent and a cross-linking agent such as glutaraldehyde.

Bernacca et al. disclose a method of modifying pericardium tissue comprising treating the tissue with acyl azide and glutaraldehyde.

Claims 1-3, 10, 11, 34, 38-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,660,692 [B].

US 5,660,692 disclose a method of treating collagen or a mixture of GAGs and collagen (col. 19, l. 55-60) which may be used for lens implant or other implants with a heterofunctional azide reagent (col. 9, ls. 10-20) and glutaraldehyde (col. 18, ls. 20-22).

Claims 1-6, 10, 11, 12, 40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 6,166,184[C].

The claims are directed to a one step treatment of a tissue with a water soluble carbodiimide @ pH 6.9-7.9.

US 6,166,184 discloses the treatment of a tissue for use as a heart valve with a carbodiimide (col. 8, ls. 27-36) at a pH of 4-9 (col. 9, l. 1).

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Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1–6, 10, 11, 34 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,017,741 [D].

The claims are directed to a method of treating an implantable biological tissue comprising contacting the tissue with a carbohydrate oxidizing agent.

The references are relied upon as explained below.

US 6,017,741 discloses the use of periodate to oxidize and modify the surface of a tissue such as bone, skin etc.. for use in vascular grafts, etc.. (col. 6, ls. 45 and 54).

One of ordinary skill in the art would have been motivated at the time of invention to perform the claimed process in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Allowable Subject Matter

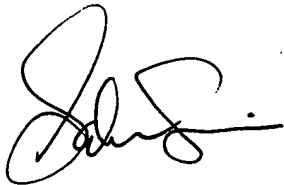
Claims 43 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claims 46 and 47 are allowable.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized, cursive script.

Sandra Saucier
Primary Examiner
Art Unit 1651
April 27, 2004